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Atty. Docket No.: 6753.US.02
Amendment and Response
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Arguments

Claims 1-30 are pending. Claims 1,5, 15-22 and 26 (all in part), 3, 7, 10, 13, 24, 28 and 30 are withdrawn from consideration. Claims 1, 5, 15-22, and 26 (all in part), 2, 4, 6, 8, 9, 11, 12, 14, 23, 25, 27 and 29 are rejected.

Claim Objections

Claim 1 is objected because is not numbered. Claim 1 has been amended.

Claims 15 to 21 have been voluntarily amended to conform to proper dependency language.

Claim Rejections – 35 U.S.C. § 103.

Applicants respectfully submit that the rejection under 35 U.S.C. § 103 of claims 1, 5, 22 and 26 (all in part), 2, 4, 6, 8, 9, 11, 12, 14, 23, 25, 27, and 29 is in error because the combination of references does not present a *prima facie* case of obviousness of the claimed invention.

1. The legal standard under 35 U.S.C. § 103.

It is well established law that the PTO has the burden under 35 U.S.C. § 103 to establish a case of a *prima facie* obviousness. To satisfy this burden, an Examiner must identify both (i) a suggestion to modify a primary reference in accordance with the teachings of one or more secondary references to achieve the claimed invention and (ii) a reasonable expectation of success in making and using the modified procedure (In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)).

Moreover, an Examiner may not use an applicant's disclosure as a guide or template to select elements from prior art references which, when combined together arrive at the claimed invention (In re Fritch, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992)).

2. The Examiner erred in combining the references of Glase *et al.*, Zorn *et al.*, and Sanner to reject claims 1, 5, 22 and 26 (all in part), 2, 4, 6, 8, 9, 11, 12, 14, 23, 25, 27, and 29, because the references contain no disclosure that suggests their combination or a reasonable expectation of success.

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Glase *et al.*, teaches that agonists with higher selectivity for the D4 dopamine receptor than for the D2 dopamine receptors may provide a useful tool in determining the role or contribution of D4 receptors in schizophrenia

Zorn *et al.*, teaches that since antipsychotic drugs bind with high affinity also to the D4 dopamine receptor, in addition to the D2 dopamine receptor, the D4 receptor may be a target for development of future antipsychotic drugs.

The reference of Glase and the reference of Zorn fail to teach or suggest, alone or in combination, the use of centrally acting D4 agonists to treat sexual dysfunction.

Sanner teaches compounds that bind to human dopamine D4 receptors expressed in clonal cell lines. The binding is detected by the ability of the compounds of Sanner's invention to inhibit the binding of [3H] spiperone. Sanner provides no teaching that the novel compounds of formula I of his invention are agonists or antagonists to the D4 dopamine receptor. The reference simply indicates that the compounds are dopamine agents based on the results of the binding assays. The Examiner suggests that a skilled in the art would be motivated to employ Sanner's claimed compounds to treat erectile dysfunction because dopamine is a known peripheral vasodilator.

Applicants believe that a key to understanding the nonobviousness of the present invention lies in recognizing the differences between the cited references and the subject matter claimed in the present invention. The present invention claims compounds that are D4 dopamine receptor agonists, which promote a centrally mediated erectile response in male rats with a reduced emetic effect.

Applicants respectfully state that the Examiner fails to consider that the compounds of the present invention are selective D4 agonists and induce erectile response in rats via a centrally mediated mechanism and not through peripheral vasodilatation.

Therefore, the Examiner has failed to establish a case of a *prima facie* obviousness, because (a) there is no teaching or suggestion in Sanner to use the D4 dopamine agents disclosed in Sanner as centrally active agents to treat sexual dysfunction, and (b) there is no teaching or suggestion in Sanner alone or in combination with Glase *et al.*, or Zorn *et al.*, to modify these references in order to achieve the subject

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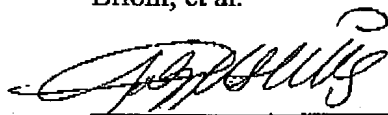
matter claimed in the present invention. Sanner alone or in combination with Glase *et al*, or Zorn *et al.*, does not teach or suggest compounds that are selective D4 agonists, which induce erectile response by acting selectively on central D4 dopamine receptors.

3. Conclusion.

Applicants respectfully submit that, in view of the above, the pending claims in the present application are patentable over the cited prior art and urge allowance of the claims.

Respectfully submitted,
Brioni, et al.

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